

## REMARKS/ARGUMENT

### Description of Amendments

New Claims 46-48 are added, and Claims 1, 21-33 and 39 are canceled. Accordingly, Claims 17, 42 and 46 are the three remaining claims written in independent claim format.

Support for Claims 46-48 may be found on pages 17-18 of Applicants' specification.

Claims 21 and 22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by XP-000980708 ("XP"). These claims are canceled. The rejections are therefore moot.

Claims 23 and 24 stand rejected under 35 U.S.C. § 102(e) as being anticipated by US2003/0196596 ("*Nishi*"). These claims are canceled. The rejections are therefore moot.

The rejection(s) of Claim 1 is also moot since Claim 1 was canceled.

### Confirmation of Examiner's Previous Consideration of Pending Applications

The undersigned wishes to thank Examiner Edwards for the voice mail message left on August 5, 2008 concerning the cited pending patent applications that were crossed off in the returned copy of Applicants' PTO Form 1449. As discussed earlier, the Examiner had considered these references, but had crossed them off (as opposed to initialing them per MPEP § 609) so that they would not be inadvertently printed on the issued patent.

In the August 5, 2008 voice mail message, the Examiner offered to initial the references (some of which have since issued as patents) to thereby indicate the Examiner's consideration of the references if Applicants would provide a duplicate PTO form 1449. Enclosed is this duplicate PTO form 1449. Applicants kindly ask that the Examiner please place her initials adjacent those references that have been fully considered and return a photocopy of the initialed enclosed PTO Form 1449 with the next office action.

### Rejections of Claims 17 and 42 under 35 U.S.C. §§ 102(b), 103(a)

Claims 10, 14 and 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over XP, *Hijkema* and *Heller*.

As best understood, the Office relies on *Hijkema* to sustain a rejection of Claim 17 based on the reasoning that it would have been obvious “to provide a temperature controller”. Page 5. As to *Heller*, the Office found that it would have been obvious to provide “a mandrel manipulative device . . . in order to rotating [sic] as well as vibrating [sic] the stent causing pressure to transfer coating material from the porous applicator to the surface of the stent”. Pages 7-8. Applicants respectfully traverse the rejections for at least the following reasons.

*Hijkema* is directed to controlling the temperature of a work piece to enhance the hardness or resilience. The purpose of varying the temperature is to prevent damage to a coating that was previously applied to the work piece:

[T]he hardness or resilience of the coating of a work-piece is temporarily increased by adjusting its preexisting temperature to be closer to its glass transition temperature. Then, while the coating is in this temporarily hardened or more resilient state, the force required to reconfigure the work-piece is applied against the coating. By temporarily increasing the hardness of the coating through its change in temperature, the coating is better able to withstand the forces and pressures exerted upon it during the reconfiguration of the work-piece. Thus, the coating is more likely to remain intact both during the remainder of the manufacturing of the work-piece and after the work-piece has been completely manufactured and is employed for its intended purpose.

Col. 3, ll. 12-25. *See also* cols. 1-2; col. 5, ll. 9-24; col. 6, ll. 31-44 and 60+ to col. 7, line

12.

*Heller* is directed to an apparatus that applies a coating to an prosthesis that is subjected to a centrifugal force, i.e., spinning, and/or vibratory force while being disposed within a spray chamber. *See e.g.*, para. [0022].

Claim 17 is directed to a system for coating an implantable medical device with a coating composition, including the features of a reservoir holding a coating composition; an applicator including a coating surface and a porous region in fluid communication with the coating composition in the reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface; a temperature controller in communication with the applicator, the support element or the reservoir for heating or cooling the coating composition; and further comprising a pressurizing device in communication with the applicator

or the reservoir for enhancing the conveyance of the coating composition from the reservoir to the coating surface.

In contrast to *Hijlkema*, Applicants' system is configured to coat a prosthesis using a temperature controller. *Hijlkema* modifies the surface temperature of a work piece to make the coating more resistant to chipping or cracking. For instance, by making the surface more cold or hot, locally applied loads, especially in high stress areas, will have a reduced tendency to create imperfections in the previously coated surface of the work piece. *See* Col. 3, ll. 12-25.

It appears that the Office has concluded that the standard for obviousness may be met by a mere showing that all elements in the claim were separately known and capable of being combined to re-create the invention, because at page 5 the Official Action concludes that one of ordinary skill would have been motivated to use a temperature controller in any part of a stent manufacturing system apparatus in view of the teaching in *Hijlkema*. Thus, according to the Official Action, *Hijlkema* would have rendered obvious any use of a temperature controller used in connection with manufacturing a stent, regardless of the purpose. ***If Applicants' understanding of the Office's reliance on this reference is incorrect, it is kindly asked that the Office please clarify how it believes Hijlkema is relevant to the present analysis.***

Applicants respectfully submit that the basis for this rejection is improper. For instance, there is nothing in *Hijlkema* to suggest that a temperature controller, configured as described in this reference, would have been suitable for enhancing the loading of a coating surface and thus yielding a predictable outcome in light of the teaching in *Hijlkema*. Applicants respectfully remind the Office that it is not sufficient to simply identify a missing element in the same field of the invention. The substantive law requires that there be some reason why one of ordinary skill would have found it obvious to make the invention.

Because the rejection is supported by nothing more than a capacity to combine features in the prior art, the rejection under Section 103 is improper. Withdrawal of the rejection of Claim 17 under Section 103 is earnestly solicited.

Claim 17 also includes the feature of a pressurizing device in communication with the applicator or the reservoir for enhancing the conveyance of the coating composition from the

reservoir to the coating surface. In rejecting this claim, the Office concludes that a pressurizing device as described is taught by *Heller* because the reference describes a process by which a stent is spun and/or vibrated when it is being sprayed by a coating.

Not only is *Heller* referring to a different type of coating system, i.e., one that uses a spray, the reference is totally devoid of a pressurizing device in communication with the applicator or the reservoir for enhancing the conveyance of the coating composition from the reservoir to the coating surface. A rejection under Section 103 requires at least that the prior art, when combined, disclose all features of a claimed invention. *See* MPEP § 2141. However, it is clear that nowhere does *Heller* describe or even suggest a pressure device as described in Claim 17. ***Is it the Office's contention that a vibrating stent would have rendered obvious a pressuring device for enhancing the conveyance of the coating composition from the reservoir to the coating surface? If this is indeed the case, Applicants kindly ask that the Examiner confirm this understanding of the 5/28/08 Official Action.***

As the combined art nowhere teaches all aspects of Claim 17, Applicants respectfully ask that the rejection of Claim 17 be withdrawn.

Claim 42 includes the feature of wherein the reservoir has walls and the walls, the porous portion and the coating portion form a closed space containing at least a portion of the coating composition contained in the reservoir, further including: a pressure device in fluid communication with the space and configured for regulating the coating composition conveyed to the coating surface by regulating the pressure in the space.

For similar reasons as those given above, Applicants respectfully ask that all standing rejections of Claim 42 under Sections 102 and 103 be withdrawn.

Claims 2-6, 8-16, 18-20, 40, 41, 43, 44, 45, 47, and 48

Claims 2-6, 8-16, 18-20, 40, 41, 43, 44, 45 depend from Claims 17 and 42, respectively, and recite additional features that further distinguish Applicants' invention over the art of record. However, it is not necessary to point out the additional features recited in these dependant claims. Because Claims 2-6, 8-16, 18-20, 40, 41, 43, 44, 45 depend from allowable claims, they

are also allowable. For this reason, Applicants ask that all standing rejections of Claims 2-6, 8-16, 18-20, 40, 41, 43, 44, 45 under 35 U.S.C. §§ 102 and 103, respectively, be withdrawn.

New Claims 46-48

Claim 46 is directed to a system for coating an implantable medical device with a coating composition, comprising: a reservoir holding a coating composition; an applicator including a coating surface and a porous region in fluid communication with the coating composition in the reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface; a support element to support an implantable medical device in close proximity to or in contact with the coating surface of the applicator; and a pressure apparatus configured to supply a gas to, and being in fluid communication with the coating composition so as to enhance the loading of the coating surface. Nowhere does the art of record, separately or in combination teach or suggest the features of Claim 46. Claims 47 and 48 are also patentable, at least because these claims depend from Claim 46.

For the above reasons, allowance for Claims 2-6, 8-16, 17-20, 40, 41, 43-48 is earnestly solicited.

Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Date:

8/28/08

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<b>FORM PTO-1449 (Modified)</b>		US DEPARTMENT OF COMMERCE		Docket No. 050623.328		Application No. 10/747,996		
<b>INFORMATION DISCLOSURE CITATION in an Application</b> (Use several sheets if necessary)				Applicant Chen et al.				
				Filing Date December 29, 2003		Group Art Unit 3738		
<b>U.S. PATENT DOCUMENTS</b>								
Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate	
	A1	7,338,557	3/4/08	Chen et al.				
	A2	7,258,891	8/21/07	Pacetti				
	A3	7,323,210	1/29/08	Castro et al.				
	A4	7,056,591	6/6/06	Pacetti et al.				
	A5	7,198,675	4/3/07	Fox et al.				
	A6	7,220,816	4/22/07	Pacetti et al.				
<b>U.S. PATENT APPLICATIONS</b>								
Examiner Initial	Ref. No.	Document Number	Filing Date of Application	Name	Class	Subclass		
	A7	10/255,913	9/26/02	Tang et al.				
	A8	10/304,669	11/25/02	Madriaga et al.				
	A9	10/317,435	12/11/02	Hossainy et al.				
<b>U.S. PATENT APPLICATION PUBLICATION DOCUMENTS</b>								
Examiner Initial	Ref. No.	Document Number	Date of Publication	Name	Class	Subclass	Filing Date if Appropriate	
	A10	2005-0137381	6/23/05	Pacetti				
	A11							
<b>FOREIGN PATENT DOCUMENTS</b>								
Examiner Initial	Ref. No.	Document Number	Date of Publication	Country	Class	Subclass	Translation	
							Yes	No
	B1							
	B2							
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)</b>								
	C1							
	C2							
EXAMINER				DATE CONSIDERED				
EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 608; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant								

BC	A789	2005/0065501	3/24/05	Wallace			9/23/03
	A790	2005/0065545	3/24/05	Wallace			9/23/03
	A791	2005/0064088	3/24/05	Fredrickson			9/24/03
	A792	2005/0074545	4/7/05	Thomas			9/29/03
	A793	2005/0074406	4/7/05	Couvillon, Jr. et al.			10/3/03
✓	A794	2005/0079274	4/14/05	Palasis et al.			10/14/03

## U.S. PATENT APPLICATION DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Filing	Name	Class	Subclass	
	A795	10/255,913	9/26/02	Tang et al.			
	A796	10/304,669	11/26/02	Madriaga et al.			
	A797	10/317,435	12/11/02	Hossainy et al.			
	A798	10/322,255	12/17/02	Chen et al.			
	A799	10/409,410	4/7/03	Pacetti			
	A800	10/439,415	5/15/03	Perng			Abandoned
	A801	10/602,487	6/23/03	Castro et al.			
	A802	10/638,250	7/30/03	Pacetti et al.			
	A803	10/676,545	9/30/03	Fox et al.			
	A804	10/738,704	12/16/03	Pacetti et al.			
	A805	10/741,214	12/19/03	Pacetti			

## FOREIGN PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Publication	Country	Class	Subclass	Translation	
							Yes	No
BC	B1	CA 2 008 312	7/26/90	Canada				
	B2	CA 2 007 648	4/17/91	Canada				
	B3	CA 1 322 628	10/5/93	Canada (Abstract)				
	B4	CA 1 336 319	7/18/95	Canada (Abstract)				
	B5	CA 1 338 303	5/7/96	Canada				
	B6	DE 042 24 401	1/27/94	Germany (English Abstract)				
	B7	DE 044 07 079	9/29/94	Germany (English Abstract)				
	B8	DE 197 31 021	1/21/99	Germany (English Abstract)				
	B9	DE 199 16 086	10/14/99	Germany (English Abstract)				
	B10	DE 198 56 983	12/30/99	Germany (English Abstract)				
✓	B11	EP 0 108 171	5/16/84	EPO				